UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK		
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GOJO INDUSTRIES, INC.,	:	ECF Case
Plaintiff,	:	Case No.: 15-cv-2946(PAC)
v.	:	
INNOVATIVE BIODEFENSE, INC.; and AQUARIUS GLOBAL ENERGY PARTNERS, LLC,	: : : : : : : : : : : : : : : : : : : :	
Defendants.	:	
	X	

PLAINTIFF GOJO INDUSTRIES, INC.'S REPLY TO DEFENDANT INNOVATIVE BIODEFENSE, INC.'S COUNTERCLAIM

Plaintiff/Counterclaim Defendant, GOJO Industries, Inc. ("Plaintiff" or "GOJO"), by and though counsel, and for its Reply to the Counterclaim of Defendant/Counterclaim Plaintiff, Innovative Biodefense, Inc. ("Defendant" or "IBD"), hereby answers as follows:

- 1. GOJO admits the allegations contained in Paragraph 1 of the Counterclaim.
- 2. GOJO admits the allegations contained in Paragraph 2 of the Counterclaim.
- 3. Paragraph 3 of the Counterclaim contains legal conclusions to which no response is required. Answering further, GOJO admits that this Court has jurisdiction over the parties to this action.
- 4. Paragraph 4 of the Counterclaim contains legal conclusions to which no response is required. Answering further, GOJO admits that this Court has personal jurisdiction over it. GOJO denies the remainder of the allegations contained in Paragraph 4 of the Counterclaim.
 - 5. GOJO denies the allegations contained in Paragraph 5 of the Counterclaim.
 - 6. GOJO admits the allegations contained in Paragraph 6 of the Counterclaim.

- 7. In response to the allegations contained in Paragraph 7 of the Counterclaim, GOJO admits that it manufactures and offers for sale PURELL® Sanitizer hand hygiene products, and that IBD purports to manufacture certain hand hygiene products. GOJO denies the remainder of the allegations contained in Paragraph 7 of the Counterclaim.
 - 8. GOJO admits the allegations contained in Paragraph 8 of the Counterclaim.
 - 9. GOJO denies the allegations contained in Paragraph 9 of the Counterclaim.
- 10. In response to the allegations contained in Paragraph 10 of the Counterclaim, GOJO admits that there is an Exhibit A attached to the Counterclaim but that this document speaks for itself and no response thereto is required. Answering further, GOJO does not advertise or make public statements that its PURELL® Sanitizer products are "approved" by the FDA, nor does it authorize or instruct any of its distributors, manufacturer's representatives, or agents to make such statements, and that any such statements were made without GOJO's knowledge or approval and have been removed. GOJO denies the remainder of the allegations contained in Paragraph 10 of the Counterclaim.
 - 11. GOJO denies the allegations contained in Paragraph 11 of the Counterclaim.
- 12. In response to the allegations contained in Paragraph 12 of the Counterclaim, GOJO admits that IBD purports to quote a portion of the CDC's website but that the quotation is taken out of context and fails to refer to or incorporate other information relative to the use of the CDC's logo. GOJO denies the remainder of the allegations contained in Paragraph 12 of the Counterclaim.
- 13. In response to the allegations contained in Paragraph 13 of the Counterclaim, GOJO admits that IBD purports to quote a portion of the WHO's website but that the quotation is taken out of context and fails to refer to or incorporate other information relative to the use of

the WHO's emblem. GOJO denies the remainder of the allegations contained in Paragraph 13 of the Counterclaim.

- 14. In response to the allegations contained in Paragraph 14 of the Counterclaim, GOJO admits that IBD purports to quote a portion of Health Canada's website but that the quotation is taken out of context and fails to refer to or incorporate other information relative to the use of Health Canada's emblems. GOJO denies the remainder of the allegations contained in Paragraph 14 of the Counterclaim.
- 15. In response to the allegations contained in Paragraph 15 of the Counterclaim, GOJO admits that there is an Exhibit B attached to the Counterclaim that represents screenshots from a video posted on GOJO's website about the importance of handwashing. The referenced logos appear on the screen for less than 5 seconds while the voiceover states that those agencies "agree on the importance of hand hygiene." No other mention is made of these agencies for the entirety of the three-minute video, nor does GOJO claim that these agencies "endorse" or "approve" its products. GOJO denies the remainder of the allegations contained in Paragraph 15 of the Counterclaim.
 - 16. GOJO denies the allegations contained in Paragraph 16 of the Counterclaim.
- 17. The allegations in Paragraph 17 of the Counterclaim contain overly broad and generalized statements purporting to state conclusions as to how to conduct a "well-controlled" study. In response to these allegations, GOJO admits that it conducts appropriate and "well-controlled" studies. GOJO denies the remainder of the allegations contained in Paragraph 17 of the Counterclaim which purport to create a "one size fits all" approach to scientific inquiry.
- 18. The allegations in Paragraph 18 of the Counterclaim contain overly broad and generalized statements purporting to state conclusions as to how to conduct a "well-controlled"

study. In response to these allegations, GOJO admits that it conducts appropriate and "well-controlled" studies. GOJO denies the remainder of the allegations contained in Paragraph 18 of the Counterclaim which purport to create a "one size fits all" approach to scientific inquiry.

- 19. The allegations in Paragraph 19 of the Counterclaim contain overly broad and generalized statements purporting to state conclusions as to how to conduct a "well-controlled" study. In response to these allegations, GOJO admits that it conducts appropriate and "well-controlled" studies. GOJO denies the remainder of the allegations contained in Paragraph 19 of the Counterclaim which purport to create a "one size fits all" approach to scientific inquiry.
- 20. The allegations in Paragraph 20 of the Counterclaim contain overly broad and generalized statements purporting to state conclusions as to how to conduct a "well-controlled" study. In response to these allegations, GOJO admits that it conducts appropriate and "well-controlled" studies. GOJO denies the remainder of the allegations contained in Paragraph 20 of the Counterclaim which purport to create a "one size fits all" approach to scientific inquiry.
- 21. The allegations in Paragraph 21 of the Counterclaim contain overly broad and generalized statements purporting to state conclusions as to how to conduct a "well-controlled" study. In response to these allegations, GOJO admits that it conducts appropriate and "well-controlled" studies. GOJO denies the remainder of the allegations contained in Paragraph 21 of the Counterclaim which purport to create a "one size fits all" approach to scientific inquiry.
- 22. The allegations in Paragraph 22 of the Counterclaim purport to state a conclusion or rule as to how to conduct a "well-controlled" study. To the extent a response is required, GOJO denies the allegations contained in Paragraph 22 of the Counterclaim which purports to create a "one size fits all" approach to scientific inquiry.

- 23. The allegations in Paragraph 23 of the Counterclaim contain overly broad and generalized statements purporting to state conclusions as to how to conduct a "well-controlled" study, with the principle cited being applicable only to new drug approvals. In response to these allegations, GOJO admits that it conducts appropriate and "well-controlled" studies. GOJO denies the remainder of the allegations contained in Paragraph 23 of the Counterclaim.
- 24. GOJO denies the allegations contained in Paragraph 24 of the Counterclaim. Answering further, without intending to deny that the studies referenced in sub-parts (a) through (e) of Paragraph 24 exist, GOJO states that those sub-parts contain unsupported attorney argument and conclusory statements regarding the reliability of the referenced studies and, to the extent a response is required, GOJO denies the allegations set forth therein.
- 25. In response to the allegations contained in Paragraph 25 of the Counterclaim, GOJO admits that it conducts "well-controlled" studies which are properly designed with respect to the question at issue. GOJO denies the remainder of the allegations contained in Paragraph 25 of the Counterclaim.
- 26. The allegations contained in Paragraph 26 of the Counterclaim purport to restate a portion of a statement allegedly made by the FDA in 2005 which is incomplete, out of context, and to which no response is required. To the extent a response is required, GOJO denies the remainder of the allegations contained in Paragraph 26 of the Counterclaim.
- 27. GOJO denies the allegations contained in Paragraph 27 of the Counterclaim. Answering further, without intending to deny that Exhibits C through H referenced in sub-parts (a) through (g) of Paragraph 27 are attached to the Counterclaim, GOJO states that those sub-parts contain unsupported attorney argument and conclusory statements regarding the reliability

of the referenced studies and, to the extent a response is required, GOJO denies the allegations set forth therein.

- 28. GOJO denies the allegations contained in Paragraph 28 of the Counterclaim.
- 29. In response to the allegations contained in Paragraph 29 of the Counterclaim, GOJO admits that its PURELL® Sanitizer products are safe and effective pursuant to the standards set forth in the TFM. Answering further, Paragraph 29 makes conclusory allegations regarding the TFM and the NDA process which require no response. GOJO denies the remainder of the allegations contained in Paragraph 29 of the Counterclaim.
 - 30. GOJO denies the allegations contained in Paragraph 30 of the Counterclaim.
- 31. To the extent the allegations contained in Paragraph 31 of the Counterclaim attempt to summarize or restate certain articles or scientific studies, those publications speak for themselves and no response is necessary. Answering further, GOJO denies that it markets dual-active ingredient hand sanitizer products under the TFM, and further denies that its hand sanitizer products contain triclosan. Without intending to deny that there is an Exhibit I attached to the Counterclaim, GOJO denies the remainder of the allegations contained in Paragraph 31 of the Counterclaim.
 - 32. GOJO denies the allegations contained in Paragraph 32 of the Counterclaim.
 - 33. GOJO denies the allegations contained in Paragraph 33 of the Counterclaim.
- 34. Without intending to deny that there is an Exhibit J attached to the Counterclaim, GOJO denies the allegations contained in Paragraph 34 of the Counterclaim. Answering further, the document attached as Exhibit J speaks for itself.
 - 35. GOJO denies the allegations contained in Paragraph 35 of the Counterclaim.

- 36. To the extent Paragraph 36 of the Counterclaim purports to restate a portion of the document attached as Exhibit J, that document speaks for itself and no response is required. GOJO denies the remainder of the allegations contained in Paragraph 36 of the Counterclaim.
- 37. Paragraph 37 of the Counterclaim purports only to restate a portion of the document attached as Exhibit J and, thus, no response is required other than for GOJO to deny any wrongdoing.
 - 38. GOJO denies the allegations contained in Paragraph 38 of the Counterclaim.
- 39. Paragraph 39 of the Counterclaim purports only to restate a portion of the document attached as Exhibit J and, thus, no response is required other than for GOJO to deny any wrongdoing.
 - 40. GOJO denies the allegations contained in Paragraph 40 of the Counterclaim.
- 41. To the extent Paragraph 41 of the Counterclaim purports to restate a portion of the document attached as Exhibit J, that document speaks for itself and no response is required. GOJO denies the remainder of the allegations contained in Paragraph 41 of the Counterclaim.
- 42. To the extent Paragraph 42 of the Counterclaim purports to restate a portion of the document attached as Exhibit J, that document speaks for itself and no response is required. GOJO denies the remainder of the allegations contained in Paragraph 42 of the Counterclaim.
- 43. To the extent Paragraph 43 of the Counterclaim, including sub-parts (a) through (f), purports to restate a portion of the document attached as Exhibit J, that document speaks for itself and no response is required. Answering further, sub-parts (a) through (f) of Paragraph 43 contain inconsistent and unsupported attorney argument and conclusions to which no response is required. GOJO denies the remainder of the allegations contained in Paragraph 43 of the Counterclaim.

- 44. To the extent Paragraph 44 of the Counterclaim purports to restate a portion of the document attached as Exhibit J, that document speaks for itself and no response is required. GOJO denies the remainder of the allegations contained in Paragraph 44 of the Counterclaim.
- 45. Without intending to deny that there is an Exhibit K attached to the Counterclaim, GOJO denies the allegations contained in Paragraph 45 of the Counterclaim. Answering further, the document attached as Exhibit K speaks for itself.
 - 46. GOJO denies the allegations contained in Paragraph 46 of the Counterclaim.
- 47. To the extent Paragraph 47 of the Counterclaim purports to restate a portion of the document attached as Exhibit K, that document speaks for itself and no response is required. GOJO denies the remainder of the allegations contained in Paragraph 47 of the Counterclaim.
- 48. To the extent Paragraph 48 of the Counterclaim, including sub-parts (a) through (d), purports to restate a portion of the document attached as Exhibit K, that document speaks for itself and no response is required. Answering further, sub-parts (a) through (f) of Paragraph 48 contain inconsistent and unsupported attorney argument and conclusions to which no response is required. GOJO denies the remainder of the allegations contained in Paragraph 48 of the Counterclaim.
- 49. To the extent Paragraph 49 of the Counterclaim purports to restate a portion of the document attached as Exhibit K, that document speaks for itself and no response is required. GOJO denies the remainder of the allegations contained in Paragraph 49 of the Counterclaim.
- 50. The allegations contained in Paragraph 50 of the Counterclaim purport to state argument and legal conclusions regarding the FDA's rulemaking authority pursuant to the TFM which require no response other than for GOJO to deny any wrongdoing. To the extent further

response is required, GOJO denies the remainder of the allegations contained in Paragraph 50 of the Counterclaim.

- 51. The allegations contained in Paragraph 51 of the Counterclaim purport to state argument and legal conclusions regarding the FDA's rulemaking authority pursuant to the TFM which require no response other than for GOJO to deny any wrongdoing. GOJO denies the remainder of the allegations contained in Paragraph 51 of the Counterclaim.
- 52. The allegations contained in Paragraph 52 of the Counterclaim purport to state argument and legal conclusions and comment concerning the FDA's proposed rules pursuant to the TFM which require no response other than for GOJO to deny any wrongdoing. To the extent further response is required, GOJO denies the remainder of the allegations contained in Paragraph 52 of the Counterclaim.
 - 53. GOJO denies the allegations contained in Paragraph 53 of the Counterclaim.
- 54. GOJO restates and reavers each and every answer and defense, as if fully set forth herein, in response to Paragraph 54 of the Counterclaim.
 - 55. GOJO denies the allegations contained in Paragraph 55 of the Counterclaim.
 - 56. GOJO denies the allegations contained in Paragraph 56 of the Counterclaim.
 - 57. GOJO denies the allegations contained in Paragraph 57 of the Counterclaim.
 - 58. GOJO denies the allegations contained in Paragraph 58 of the Counterclaim.
 - 59. GOJO denies the allegations contained in Paragraph 59 of the Counterclaim.
 - 60. GOJO denies the allegations contained in Paragraph 60 of the Counterclaim.
 - 61. GOJO denies the allegations contained in Paragraph 61 of the Counterclaim.
 - 62. GOJO denies the allegations contained in Paragraph 62 of the Counterclaim.

- 63. GOJO restates and reavers each and every answer and defense, as if fully set forth herein, in response to Paragraph 63 of the Counterclaim.
 - 64. GOJO denies the allegations contained in Paragraph 64 of the Counterclaim.
 - 65. GOJO denies the allegations contained in Paragraph 65 of the Counterclaim.
 - 66. GOJO denies the allegations contained in Paragraph 66 of the Counterclaim.
- 67. GOJO restates and reavers each and every answer and defense, as if fully set forth herein, in response to Paragraph 67 of the Counterclaim.
 - 68. GOJO denies the allegations contained in Paragraph 68 of the Counterclaim.
 - 69. GOJO denies the allegations contained in Paragraph 69 of the Counterclaim.
 - 70. GOJO denies the allegations contained in Paragraph 70 of the Counterclaim.
 - 71. GOJO denies the allegations contained in Paragraph 71 of the Counterclaim.
- 72. GOJO restates and reavers each and every answer and defense, as if fully set forth herein, in response to Paragraph 72 of the Counterclaim.
 - 73. GOJO denies the allegations contained in Paragraph 73 of the Counterclaim.
 - 74. GOJO denies the allegations contained in Paragraph 74 of the Counterclaim.
 - 75. GOJO denies the allegations contained in Paragraph 75 of the Counterclaim.
 - 76. GOJO denies the allegations contained in Paragraph 76 of the Counterclaim.
 - 77. GOJO denies the allegations contained in Paragraph 77 of the Counterclaim.
 - 78. GOJO denies the allegations contained in Paragraph 78 of the Counterclaim.
- 79. GOJO denies all allegations in the Counterclaim not specifically admitted hereinabove.
- 80. GOJO denies that IBD is entitled to any of the relief it seeks in its claims against GOJO.

AFFIRMATIVE DEFENSES

- 1. The Counterclaim fails to state a claim upon which relief can be granted.
- 2. The Counterclaim is barred, in whole or in part, by the doctrines of laches, waiver, and/or estoppel.
 - 3. IBD has failed to minimize and/or mitigate any alleged damages.
- 4. At all relevant times GOJO conducted itself in a commercially reasonable manner.
 - 5. Some or all of IBD's claims are barred by the applicable statute(s) of limitations.
 - 6. The damages IBD seeks are speculative and, therefore, barred.
- 7. IBD's Counterclaim is barred by operation of accord, satisfaction, and/or settlement, and/or payment, release, and compromise.
 - 8. Any equitable relief sought is barred by IBD's unclean hands.
- 9. The occurrences and damages alleged in the Counterclaim were caused by negligence, breach of duty, and/or acts or omissions of other parties or persons who may or may not be parties to this action, including intervening or superseding acts, over whom GOJO has no control and for whom it is not responsible in law.
 - 10. This Court lacks subject matter jurisdiction over some of the claims to this action.
 - 11. All of GOJO's actions were privileged or otherwise justified.
- 12. The statements or representations at issue in the Counterclaim are true and, therefore, IBD is barred from pursuing said claims.
- 13. IBD's claims based on alleged statements included in the Counterclaim are barred by the First Amendment of the U.S. Constitution and state law protections afforded to free speech.

14. IBD's claims based on alleged statements included in the Counterclaim are matters of opinion and/or puffery and are protected by law.

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15. Defendant reserves the right to add defenses as the litigation proceeds and intends

to rely upon all affirmative defenses legally available to it at the time of trial.

WHEREFORE, having fully answered the Counterclaim, Plaintiff/Counterclaim

Defendant, GOJO Industries, Inc., prays that the Court dismiss the Counterclaim with prejudice,

award GOJO its costs and attorneys' fees and provide such other just and equitable relief the

Court deems appropriate.

Date: June 29, 2015

Respectfully submitted,

/s/ James D. Arden

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